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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,096	12/04/2001	Paul A. Clemons	385A PCT/US	8475

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EXAMINER

MONTANARI, DAVID A

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,096

Applicant(s)

CLEMONS ET AL.

Examiner

David Montanari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Furthermore, under PCT Rule 13.2 the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over prior art.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, 20, 21, 23-26, 28, 30, 34, 36, and 38, drawn to a recombinant nucleic acid encoding a CAB domain, a vector comprising a nucleic acid encoding a CAB domain, a host cell comprising a recombinant nucleic acid encoding a CAB domain, a method for producing genetically engineered host cells comprising a recombinant nucleic acid encoding a CAB domain.

Group II, claim(s) 12-19, 22, 27, 29, 31, 35, 37, and 39, drawn to a nucleic acid composition encoding a fusion protein containing one or more CAB domains, a host cell comprising a nucleic acid composition encoding two nucleic acids, a method for producing genetically engineered host cells comprising nucleic acid compositions encoding CAB domains.

Group III, claim(s) 32, drawn to a non-human animal containing host cells comprising recombinant nucleic acids encoding a CAB domain.

Group IV, claim(s) 33, drawn to a non-human animal containing host cells comprising nucleic acids encoding a nucleic acid composition.

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Group V, claim(s) 40-44, drawn to a method of multimerizing fusion proteins in a host cells comprising a nucleic acid encoding a CAB domain.

Group VI, claim(s) 45, drawn to a method for providing animal cells comprising a nucleic acid composition encoding a nucleic acid encoding a CAB domain.

Group VII, claim(s) 46-48, drawn to a kit comprising a nucleic acid composition encoding a CAB domain.

Group VIII, claim(s) 46-49, drawn to drawn to a kit comprising a nucleic acid composition encoding a CAB domain and a DNA constructs containing a cloning site in place of a heterologous domain.

Group IX, claim(s) 46, 50, drawn to drawn to drawn to a kit comprising a nucleic acid composition encoding a CAB domain and a DNA constructs containing a cloning site in place of a target gene.

The inventions listed in Group I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The special technical feature linking groups I-IX appears to be that they all relate to the nucleic acid encoding a CAB domain, comprising a portion of calcineurin A and a portion of calcineurin B, wherein the CAB domain forms a tripartite complex with an FKBP/CAB ligand and an FKBP domain.

However, Watanabe et al. (JBC 1995, Identification in the Calcineurin A Subunit of the Domain That Binds the Regulatory B Subunit. 270(1): 456-460) teach the fusion protein that consists of the calcineurin A and B subunits bound together.

Therefore, the technical feature linking the inventions of groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a recombinant nucleic acid encoding a fusion protein of the calcineurin A and B subunits, vector comprising the nucleic acid encoding a fusion protein of the calcineurin A and B subunits, a host cell comprising a nucleic acid encoding a fusion protein of the calcineurin A and B subunits, and a method for producing genetically engineered host cells comprising a recombinant nucleic acid encoding a fusion protein of the calcineurin A and B subunits.

The special technical feature of Group II is considered to be a nucleic acid composition encoding a fusion protein of the calcineurin A and B subunits, a host cell comprising a nucleic acid composition encoding two nucleic acids, a method for producing genetically engineered host cells comprising nucleic acid compositions encoding calcineurin A and B domains.

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The special technical feature of Group III is considered non-human animal containing host cells comprising recombinant nucleic acids encoding a fusion protein of the calcineurin A and B domains.

The special technical feature of Group IV is considered non-human animal containing host cells comprising nucleic acids encoding a nucleic acid composition of the calcineurin A and B domains.

The special technical feature of Group V is considered a method of multimerizing fusion proteins in a host cells comprising a nucleic acid encoding a fusion protein of the calcineurin A and B domains.

The special technical feature of Group VI is considered a method for providing animal cells comprising a nucleic acid composition encoding a nucleic acid encoding a fusion protein of the calcineurin A and B domains.

The special technical feature of Group VII is considered a kit comprising a nucleic acid composition encoding a fusion protein of the calcineurin A and B domains.

The special technical feature of Group VIII is considered a kit comprising a nucleic acid composition encoding a fusion protein of the calcineurin A and B domains and DNA constructs containing a cloning site in place of a heterologous domain.

The special technical feature of Group IX is considered a kit comprising a nucleic acid composition encoding a fusion protein of the calcineurin A and B domains and DNA constructs containing a cloning site in place of a target gene.

Accordingly, Groups I-IX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari, Ph.D whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 1-571-273-3800.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Deborah Crouch*

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